IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

In RE Application of:
Applicant: Doyle et al

Examiner: Mendez, M.
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For: Wound Irrigation and Debriding System

Assistant Commissioner of Patents
Washington, D.C. 20231

APPLICANTS STATEMENT OF A LONG-FELT NEED

I, Jacquelyn Doyle, co-applicant of the above application, have been a practicing registered nurse for 28 years, specifically qualified to function in emergency situations, such as hospital emergency rooms. As a result, I am especially familiar with the wound irrigation and debriding system currently in use, and the urgent and long-felt need in the medical-care community to provide a better and safer system. It is precisely this awareness that led myself and co-applicant Kenneth Short to invent the system described and claimed in the above-identified application.

The presently available system of wound irrigation and debriding comprises individually packaged items, i.e., a sterile field pad; a sterile bowl having a capacity, for example, of 16 oz; a sterile syringe (60 cc); and a 500 cc bottle of saline solution. These items are generally not stored together as each individually can be used for other medical operations.

When needed, the individual items must be retrieved and prepared on site, e.g., in the emergency room of a hospital, in an ambulance, in a helicopter, and the like. The items are then opened and placed on the sterile field pad. The bottle of sterile saline solution is opened, poured into the now-opened bowl and then drawn into the syringe.

The present system has a number of substantive drawbacks:

1. Securing and preparing the system is cumbersome and time-consuming.

2. Once the various sealed items are opened, the system is immediately subject to possible contamination.

3. The potential of contamination is even greater when the saline solution is poured into the now-opened bowl, and then drawn into the syringe, since it is subject to airborne contaminates falling into the bowl.

4. The field pad itself, once unsealed, is also subject to contamination as soon as it is opened. The surface on which it is placed could be in an emergency ward, a school nurse's office, an accident site, etc. If the pad or surface becomes wet from spillage while the solution is being poured into the bowl, the entire field is considered to be contaminated.

5. Irrigation in the wound itself is cumbersome because both hands are usually needed, depending on the strength of the applicator, to hold the main body of the syringe and the other to operate the plunger. It can make it difficult to control the pressure of the exiting saline solution. The result, if to little, could result in inefficient cleansing; and, if too hard, in further damage to the wound.

6. After the operation, the syringe must be disposed of in a Sharps Biohazard Waste Container, not in any container. The bottle, with any remaining saline solution, must be resealed, marked for date and time, and held for 24 hours. Any remaining solution (with could be as much as 250 cc) is also discarded.

The existing system is more fully described in Attachment A.

As can be seen, the existing system, functioning under emergency situations, and in many environments which are cramped for space and short of personnel, and where time is of the essence, poses serious problems for the patient and the health-care professional. Further, the potential for contamination is inherent.

The existing system has been long recognized by professionals in the field to pose contamination risks, be time-consuming, wasteful, increasing stress to the medical professionals and safety and discomfort concerns for the patient, not to mention the cost of disposal requirements.

Applicants have invented a system which solves these problems and fills the long-felt need for a safer, more efficient, and less costly wound irrigation unit. To their knowledge, no one else has.

A summary of Applicants' system is provided in Attachment B.

As can be noted, Applicants solve the problems described above and in their Patent Application by inventing a one-piece system dedicated exclusively to wound irrigation and debriding.

As noted in the attachment and the patent application, Applicants' system (presently referred to as the OTIS system) is designed to overcome the problems of the current system as follows:

1. The system is one-piece and therefore available for immediate use as it is stored in one place.

2. The system is not subject to contamination, as it does not consist of multiple items to be separately prepared in environments exposed to potential contamination.

3. The system is easily used by one person using one hand, leaving the other hand free to deal with the patient.

4. The container portion of the unit can be easily squeezed, allowing good volume control over the fluid being dispersed. This enhances the cleansing process and reduces patient discomfort.

5. The tapered bottle and angled tip (nozzle) allows it to reach difficult locations with minimal hand rotation. If additional saline solution is required, one simply opens a second unit.

6. The entire unit, including the sterile pad, may be discarded into any waste container. No Sharps Biohazard disposal is required.

Jacquelyne R. Doyle

Dated: 3/22/03

Current Method Of Wound Irrigation

PREP

One each of the following items are required per treatment:

Sterile field pad.
Sterile bowl, less than 1 quart.
60 cc syringe.
500 cc bottle of saline solution.

Step 1.
These items are not generally stored together as a kit or package. They are stored in there own area of a supply station because each item can be used in several other medical fields, so the first thing you have to do is collect all the items from the store room and bring them to the area you will be using them. This takes up valuable staff time, which adds to an already hectic pace, prolongs patient discomfort and wastes precious time especially in an emergency.

SET UP

Step 2.
Set up sterile field by removing the sterile pad from its packaging, open it up and place it in the area you will be working.

Step 3.
Remove sterile bowl from its packaging and place it on the sterile pad.

Step 4.
Open bottle of saline solution and carefully pour it into the bowl. If it spills onto the pad the entire field is considered contaminated. The saline solution, however, is now exposed to all airborne contaminates and any other debris that can possibly fall into the bowl.

Step 5.
Remove the syringe from its packaging.

Step 6.
Make sure the syringe plunger is depressed all the way into the main vile of the syringe. Place the tip of the syringe into the now possibly contaminated bowl of saline solution. Pull on the plunger to draw solution into the vile. This takes two hands and a good deal of strength while leaving the patient unattended. This can also be very awkward and messy(spillage) if you are performing this procedure in an ambulance, helicopter or some other type of medical vehicle.

IRRIGATE WOUND

Step 7.
Irrigate the wound by pointing the tip of the syringe at the area you wish to cleanse and then depressing the plunger forcing the solution through the tip of the syringe and onto the wound. Most times this requires two hands, depending on the size and strength of a persons hands. One hand would hold the main body of the syringe while the other operated the plunger. This can make it difficult to control the pressure of the exiting saline solution which, if too little, could result in inefficient cleansing or too hard, which could cause further damage to the wound and increase a patient's discomfort. It also makes it more difficult to reach certain parts of large wounds or areas of the body and again leaves the nurse, doctor or EMT with no means of steadying, supporting or manipulating a patient's position to assist in treatment. Therefore a second person maybe required to assist in the treatment. This can be difficult in understaffed hospitals or in emergency situations. In any event, a patient's discomfort would be prolonged while finding an assistant.

Step 8.
After the syringe is empty and if the wound is still not properly cleansed you must repeat steps 6 & 7 until it is. The syringe is only 60 cc and it typically takes 120 to 180 cc to properly cleanse a wound. Because of the awkwardness of the current method, several sterile glove changes may also be required, adding to the inconvenience, time, patient discomfort, waste and expense of the procedure. If the wound irrigation is complete go to step 9.

CLEAN UP

Step 9.
Throw the bowl, sterile field pad and all the packaging waste into any trash container. Reseal the bottle of saline solution and mark the date and time on it. It will be thrown out after 24 hrs. This could mean up to 250 cc of waste per bottle.
Pull the plunger out of the main body of the syringe, break the tip and throw all parts in to a "SHARPS BIOHAZARD WASTE CONTAINER"

The procedure is now complete.